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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/272,809	03/19/1999	JOHN CLARK LAGARIAS	23070-943	6118

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
1645	27

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)
	09/272,809	LAGARIAS, JOHN CLARK
Examiner Ja-Na Hines	Art Unit	
	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 January 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1-32 is/are allowed.

6) Claim(s) 1-32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

6) Other: _____

DETAILED ACTION

Amendment Entry

1. The amendment filed January 28, 2003 has been entered. The examiner acknowledges the amendment to the specification. Claims 5 and 33 have been amended. Claims 1-32 are under consideration in this office action.

Withdrawal of Rejections

2. The following objections and rejection have been withdrawn in view of applicants' amendments and arguments:

- a) the objection of claims 5 and 8;
- b) the enablement rejection of claims 1-32 under 35 U.S.C. 112, first paragraph;
- c) the rejection of claims 1-3, 6-7, 9-22, 25 and 27-32 under 35 U.S.C. 102(e) as being anticipated by Lagarias et al., US Patent 6,046,014; and
- d) the rejection of claims 1-3, 6-7, 9-22, 25 and 27-32 under 35 U.S.C. 102(b) as being anticipated by Lagarias et al., WO 98/05944.

Response to Arguments

3. Applicant's arguments filed January 28, 2003 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The written description rejection of claims 1-32 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons already of record.

The rejection was based on the grounds that the claims fail to recite the precise definition of the polypeptide amino acid sequences of about less than 400 amino acids and that the current generic recitation of about 190 amino acids to about 400 amino acids is insufficient to support the claims as provided by the Interim Written Description Guidelines; therefore in view of the lack of written description of the claims for failing to recite the precise definition of the polypeptides, the full breadth of the claims fail to meet the written description provision of 35 USC 112, first paragraph.

Applicants assert that that the described apoproteins comprise representative examples of apoproteins that are of about 190 to 400 amino acids that comprise lyase activity. However applicants' examples point to SEQ ID NO:1 though SEQ ID NO:9; yet SEQ ID NO: 1-8 are all sequences greater than 400 amino acids long. Therefore applicants have failed to adequately describe such apoproteins with the exception of SEQ ID NO:9. Applicants urge that claims drawn to the regions within such sequences comprising the lyase activity have been adequately described, however it is examiner's position that there is no disclosure of polypeptides having about 400 amino acid. Thus, the structure of the other polypeptides is not defined. The skilled artisan cannot envision the detailed structure encompassed by the polypeptides or what amino acid

are involved. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The polypeptide and representative amino acid sequences are required.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 1330, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Therefore, applicants' arguments are not persuasive.

There must be some nexus between the structure of the protein encoded and that function of that protein. However, function cannot be predicted from the modification of the structure of the polypeptide. Without any limitation on the sequence identity besides the number of amino acids, the polypeptide comprising 190 to 400 amino acids fails to have an adequate written description. The specification fails to teach variants yet broadly claims such. There are no teachings of sequences with amino acid additions or deletions, yet the claims encompass such. Furthermore, there is no description within the specification that the claimed polypeptides exist independent of that function, i.e., lyase activity. The specification fails to teach the structure or relevant identifying characteristics of such polypeptides.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of specifically identified SEQ ID NO:9, the skilled artisan cannot envision the detailed structure of the claimed polypeptides, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation despite applicants arguments to the contrary. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Thus, the structure of these polypeptides is not defined. The skilled artisan cannot envision the detailed structure of the encompassed polypeptides since the specification has not defined what the variables can be.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.

Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The claims fail to recite the reference sequence upon which the recited amino acids are based. Furthermore, there is no recitation of a reference sequence for an apoprotein comprising about 190 to 400 amino acids. Thus the written description of such apoproteins is lacking.

The instant specification does not describe the claimed invention sufficient to show that the applicant was in possession of the claimed invention. Applicants' arguments are not persuasive. Therefore, the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines *JH*
June 3, 2003

L
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER